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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/663,111	09/15/2000	Charles J. Davidson	19601-000320US	3759

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EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 04/21/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/663,111

Applicant(s)

DAVIDSON ET AL. 

Examiner

Paul B. Prebilio

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-19 and 42-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-19 and 42-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>10, 12</u> . | 6) <input type="checkbox"/> Other: _____ |

Specification

The disclosure is objected to because of the following informalities:

On page 2, line 7, the new paragraph inserted at this point in the specification uses semicolons where commas should be used so it is grammatically awkward.

On page 1 of the specification, the continuing data is confusing and it is not clear what parent applications are being relied upon for priority. In particular, the second and third paragraphs of the insert seem to be giving the priority of parent applications, and it not clear that they are being claimed in this application or whether this is just background information.

Appropriate correction is required.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not mention the new parent applications apparently being relied upon for priority as set forth in the new continuing data; see the new insert made to the continuing data made to page 1 of the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 11, 15, 54, and 58 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The new combination claims appears to lack original support for the fixed side member having a branch stent because it is not seen how the fixed side member was originally disclosed as having a branch stent thereon; see Figure 3 of the present specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 49 and 68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to claim 49, the language of the claim is unclear because it appears to be based upon some intended use manipulative steps. For this reason, it is not clear what structure is positively required by the claim language.

With regard to claim 68, "the at least one location" lacks antecedent basis from claim 50.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

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applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 7, 10, 13, 16-19, 42,44-48, and 71 are rejected under 35 U.S.C. 102(e) as being anticipated by Fischell et al (US 5,749,825). Fischell anticipates the claim language where the catheter as claimed is met by shaft (25) of Fischell (see Figure 1), the side member as claimed is met by side branch tube (24) of Fischell, the stent as claimed is met by stent (20) of Fischell. It is noted that the side member must be fixed to the shaft (25) at at least the crotch point to work and operate as shown; see Figure 3. This is due to the fact that the stent is not holding the side branch tube and the shaft to each other at the crotch point because pressure from the saddlepoint (4) biasing the branch tube and shaft apart must be counteracted upon by the crotch point attachment. Furthermore, the branch tube must be flexible and movable relative to the shaft, otherwise, it could not be advance through the main artery (1) with its separated diameter of Figure 1.

With regard to claim 13, since the side tube is made of metal, it is inherently fluoroscopically visible to some extent; see column 3, lines 15-18. Furthermore, the stent is fluoroscopically visible material.

With regard to claim 19, Applicant is directed to see column 3, lines 11-12.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-6, 49-51, 53, 56, 59-68, and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al (US 5,749,825) in view of Fischell et al (US 5,669,932). Fischell meets the claim language but fails to mark both the side tube (24) and the shaft (25), but rather marks only the shaft at (30); see Figure 3. However, Fischell teaches that it was known to mark catheters in various locations in order to enable accurate positioning of stents; see especially the abstract. Hence, it would have been obvious to mark the Fischell side tube and shaft in a similar fashion in order to enable more accurate placement of the stents thereof; see Figure 5.

With regard to claim 68, Fischell ('825) discloses a stent (40) that portion that is distal to the location in the branches where part of the attachment is proximal to the stent but lacks the entire stent being distal of the fixed location as apparently required by the present claim language. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have an attachment location proximal of the stent (see Figure 1 where shaft joins the side tube and the balloon (23)) because Applicants have not disclosed that this modification results in some advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicants' invention to perform equally well because the claims do not preclude attachments distally of the proximal end of the stent. Therefore, it would have been an obvious matter of design choice to modify Fischell to obtain the invention as specified in the claims.

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Claims 8, 11, 12, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al (US 5,749,825) in view of Richter et al (US 5,755,734). Fischell meets the claim language but fails to teach the use of the branch tube as a means to place side stent (40) in the branch artery as required by the present claims; see Figure 5 of Fischell. However, Richter teaches that it was known to use balloon catheters with guidewires in place side stents into proper position; see Figures 13-21. Hence, it is the Examiner's position that it would have been obvious to use the side branch tube (24) of Fischell as a means to place side stent (40) in place so it could be accurately and safely placed therein.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al (US 5,749,825) in view of Davila et al (US 5,851,464). Fischell meets the claim language except for the pebax and graphite catheter as claimed. However, Davila teaches that it was known to make catheters out of pebax and graphite; see column 3, lines 8-32. Hence, it is the Examiner's position that it would have been obvious to make the catheter of Fischell out of pebax and graphite for the same reasons that Davila does the same and in order to promote sliding between the catheter and guidewire.

Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al (US 5,749, 825) alone. Fischell discloses a stent (40) that portion that is distal to the location in the branches where part of the attachment is proximal to the stent but lacks the entire stent being distal of the fixed location as apparently required by the present claim language. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have

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an attachment location proximal of the stent (see Figure 1 where shaft joins the side tube and the balloon (23)) because Applicants have not disclosed that this modification results in some advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicants' invention to perform equally well because the claims do not preclude attachments distally of the proximal end of the stent. Therefore, it would have been an obvious matter of design choice to modify Fischell to obtain the invention as specified in the claims.

Claims 52, 54, 55, 58, and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al ('825) and Fischell ('932) as applied to claim 50 above, and further in view of Richter et al (US 5,755,734). Fischell ('825) fails to teach the use of the branch tube as a means to place side stent (40) in the branch artery as required by the present claims; see Figure 5 of Fischell ('825). However, Richter teaches that it was known to use balloon catheters with guidewires in place side stents into proper position; see Figures 13-21. Hence, it is the Examiner's position that it would have been obvious to use the side branch tube (24) of Fischell ('825) as a means to place side stent (40) in place so it could be accurately and safely placed therein.

Claim 57 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al ('825) and Fischell et al ('932) as applied to claim 50 above, and further in view of Davila et al (US 5,851,464). Fischell ('825) fails to disclose the pebax and graphite catheter as claimed. However, Davila teaches that it was known to make catheters out of pebax and graphite; see column 3, lines 8-32. Hence, it is the Examiner's position that it would have been obvious to make the catheter of Fischell ('825) out of pebax and

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graphite for the same reasons that Davila does the same and in order to promote sliding between the catheter and guidewire.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure

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outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9301.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.



Paul Prebilic
Primary Examiner
Art Unit 3738